

REMARKS

The examiner has rejected the claims under 35 U.S.C. § 102 in paragraphs 4, 5 and 6 of the final office action. In addition the examiner has rejected the claims under 35 U.S.C. § 103 in paragraph 7 of the final office action. Before discussing each of these rejections, applicant first wishes to thank the examiner for the courtesy extended to the below signed attorney during the interview on December 3, 2003. The following remarks constitute a separate record of the substance of the interview as well as additional comments in support of the patentability of the claimed invention.

One of the references relied upon by the examiner (Japanese patent application no. 57-105145 A) pertains to a feed additive for chickens which is said to be useful for curing dyspepsia and for improving the quality of egg and meat quality. In particular, it is said that the feed additive results in excellent thickness of shell, color of yolk and viscosity of the egg white. The feed additive includes a natural pigment such as carotene or xanthophyll. The pigment is utilized to improve the color of the yolk. The anti-dyspepsia characteristic is clearly achieved through the use of the powdered fossilized soil of marine organisms (i.e., chalk) which has an obvious anti-acid capability for combating dyspepsia. In short, the '145 reference only teaches the use of xanthophyll for its pigmentation characteristic, not for any recognized anti-dyspepsia utility. Furthermore, since the pigment is used to improve the color of the yolk, it is clear that the teaching concerning the use of xanthophyll as a feed additive only applies to non-human animals which are raised for egg and meat production.

The other two references relied upon by the examiner in the rejections are European patent application no. 0770385 A1 and WO 98/37874. These references deal with medicinal compositions for treating ulcers caused by stress or for treating inflammation of the gastrointestinal tract caused by *Helicobacter* infection. The examiner argues that EP '385 is relevant to applicant's invention because treating an ulcer will inherently provide a treatment for dyspepsia which is associated with the ulcer. Likewise the examiner urges that WO '874 is relevant because treating the

inflammation caused by the *Helicobacter* will inherently provide treatment for dyspepsia which is associated with the *Helicobacter* induced inflammation.

As noted during the interview, applicant's invention does not deal with the curing of ulcers and *Helicobacter* induced inflammation. Instead, applicant's invention is directed toward alleviating the symptoms of common indigestion which is experienced by nearly everyone at varying times without being associated with any underlying pathology such as an underlying ulcer or *Helicobacter* induced inflammation. Thus, the purpose of the invention is to alleviate the symptoms of indigestion which commonly are experienced by many individuals even in the absence of ulcers and *Helicobacter* induced inflammation. Anyone skilled in the art will therefor recognize that even if the underlying pathology (i.e., ulcer or *Helicobacter* induced inflammation) is cured, such individuals will nonetheless experience the aforementioned common form of indigestion. It is alleviating the symptoms of this common form of indigestion to which the present invention pertains. In addition the invention also provides prophylactic treatment. Prophylactic treatment is known as a preventative measure and thus the invention includes administering the claimed medicament to individuals who are susceptible to indigestion before the indigestion actually occurs. The prophylactic aspect of the invention therefore involves administering the medication before the onset of any symptoms and without any underlying pathology being diagnosed.

Turning now to the specific rejections, the examiner has rejected claims 8, 12, 13 and 15 under 35 U.S.C. § 102(b) as being anticipated by Japanese patent application no. 57-105145 A. In response to this rejection applicant has amended the claims so that they are now more particularly directed toward a method for alleviating symptoms of indigestion in a human. As discussed above, the cited reference only pertains to the use of xanthophyll as a pigment additive in an animal feed composition wherein the pigment is added for coloration to improve the color of the yolk. The rejection is no longer appropriate to the amended claim since this reference fails to disclose a method for alleviating the symptoms of indigestion in a human. In this regard

Serial No. 09/463,958

it is to be noted that humans are primate mammals whereas chickens are not even mammals. Furthermore, although cattle are mammals, they are ruminants which have a different type of digestive tract.

It is also to be noted that the composition is now more particularly defined in the claims as a medicament which "consists essentially of" the recited ingredients.

The examiner has rejected claims 8-16 under 35 U.S.C. § 102(b) as being anticipated by European application no. 0 770 385 A1. In rejecting the claims the examiner urges that the cited reference anticipates applicant's invention because the reference teaches the use of a composition containing xanthophyll for treating ulcers caused by stress. The Examiner argues that a symptom of ulcers includes indigestion and thus treating ulcers in the manner taught by EP '385 inherently involves treating a person with indigestion. Applicant has carefully considered this rejection but is most respectfully traversed for the reasons discussed below.

As noted during the interview, it is well known by those skilled in the art that indigestion is not necessarily a symptom of all ulcers. For example, ulcers in the lower part of the gastrointestinal tract such as in the colon are not believed to be associated with indigestion. Thus it does not follow that treating an ulcer necessarily involves treatment of indigestion. Moreover, curing an ulcer by the method disclosed in EP '385 will not necessarily alleviate symptoms of indigestion because patients without ulcers (including those who have been cured by the prior art method) routinely experience indigestion. As discussed above, there is usually no specific underlying pathological condition for common indigestion. In other words while the prior art might cure an ulcer, such a cure does not necessarily result in alleviation of the symptoms of indigestion since such symptoms of indigestion commonly occur in individuals in which there is no underlying pathological condition such as an ulcer. Thus, the Examiner's argument that treating ulcers caused by stress will inherently alleviate symptoms of indigestion is not

accurate. Accordingly, applicant submits that the presently claimed invention is not anticipated by the cited reference.

The Examiner has rejected claims 8-16 under 35 U.S.C. § 102 (b) as being anticipated by WO 98/37874. In rejecting the claims, the Examiner urges that the cited reference discloses administering a composition which includes Xanthophyll for treating inflammation caused by *Helicobacter pylori* bacteria. In item 6 on page 3 of the Final Office Action, the Examiner acknowledges applicant's previous argument that the reference fails to teach the claimed method because the reference only teaches the use of xanthophylls to kill the *H. pylori*. However, the Examiner nonetheless urges that the rejection is proper because *H. pylori* infection causes ulcers and a known symptom of ulcers is dyspepsia. Thus the Examiner relies on WO 98/37874 using the same line of reasoning discussed above with respect to EP '385. Accordingly, applicant submits that the rejection is improper for the same reasons noted above with respect to the rejection based upon EP '385. In this regard it is to be noted that not all *Helicobacter pylori* infections with result in dyspepsia and moreover and even if the prior art treatment cures the inflammation so that ulceration does not occur, the absence of such an ulcer does not necessarily mean that the patient will not suffer from indigestion as do many individuals who do not have an ulcer. In other words, the inherency argument used by the Examiner does not apply to the claims which are directed toward the method for alleviating the symptoms of indigestion.

Lastly, the Examiner has rejected claims 8-14 under 35 U.S.C. § 103 (a) as being unpatentable over JP '145 in view of WO '874. In rejecting the claims the Examiner acknowledges that JP '145 does not specifically teach using astaxanthin as the xanthophyll. The Examiner turns to the teaching of the secondary reference for this aspect of the invention. In this regard, the Examiner urges that WO '874 teaches the use of astaxanthin to treat infections that cause indigestion. The Examiner concludes that one of ordinary skill in the art would expect that astaxanthin could beneficially be used as the xanthophyll in the method taught by JP '145. Applicant has carefully

considered this rejection but it is most respectfully traversed for the reasons discussed below.

Firstly, JP '145 is no longer applicable to the claims in view of the amendment which limits the rejected claims to the treatment of humans. Secondly, the Examiner's statement that WO '874 teaches the use of astaxanthin to treat infections that cause indigestion, is not accurate because it does not necessarily follow that all *H. pylori* infections result in indigestion. Thirdly, the primary reference is directed to solving problems associated with animal feed additives which are fed to non-human animals used for the production of eggs and meat. The xanthophyll is used as a pigment in the animal food additive. Applicant submits that there would be no motivation for one skilled in the art to consult with the teaching of the secondary reference to solve any shortcomings with respect to the pigment additive used in the animal food additive of the primary reference. In this regard it is to be noted that the secondary reference relates to the unrelated field of antibacterial pharmaceutical compositions which are used to treat *H. pylori* infections. Clearly there would be no motivation for one skilled in the art to use the astaxanthin antibiotic contained in the composition of the secondary reference in the unrelated technology of the primary reference which used xanthophyll as a pigment. Accordingly, the necessary motivation to support an obviousness rejection is absent.

Applicant has added new claims 17-25 which parallel claims 8-16 with the exception being that the new set of claims focuses on the prophylactic utility whereas claims 8-16 focus on the alleviation of the actual symptoms of indigestion. Applicant submits that none of the prior art references, either alone or in combination with each other, disclose or suggest the prophylactic utility of claims 17-25. In this regard, it is to be noted that claims 17-25 are distinguished over JP '145 since these claims, like claims 8-16 are directed toward the treatment of humans. Furthermore, since the remaining two references teach the composition solely for the treatment of underlying pathological conditions (ulcers and infections which produce ulcers) these references

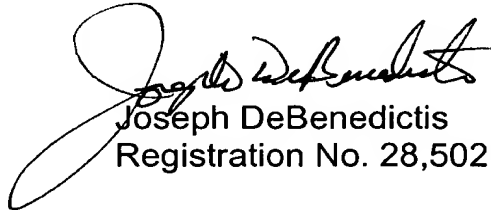
Serial No. 09/463,958

do not disclose any prophylactic utility wherein a person without any present symptoms or underlying pathological condition would be treated.

In view of the above arguments and further amendment to the claims, applicant respectfully requests reconsideration and allowance of all of the claims which are currently pending in the application.

Respectfully submitted,

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